K070382

510(k) Summary

MAY 30 2007

Submitter:	Zimmer Trabecular Metal Technology, Inc. 10 Pomeroy Road Parsippany, New Jersey 07054
Contact Person:	Jennifer P. Harakal Senior Specialist, Regulatory Affairs Telephone: (973) 576-0133 Fax: (973) 884-8795
Date:	April 25, 2007
Trade Name:	Vista®-S Device
Common Name:	Vertebral Body Replacement Device
Classification Name and Reference:	Spinal Intervertebral Body Fixation Orthosis 21 CFR § 888.3060, MQP

DEVICE DESCRIPTION

The Vista®-S Device is a box-shaped vertebral body replacement fabricated from polyetheretherketone (PEEK) that is designed to accommodate the partial replacement of a vertebral body in the thoracic and lumbar region of the spine. The device is available in a variety of cross sections and heights to accommodate variations in the individual pathology and anatomic condition of the patient. The superior and inferior surfaces of the device contain a pattern of teeth to provide for initial stability. Radiopaque markers are press fit into the device to aid in determining the location of the implant postoperatively.

INDICATIONS FOR USE

The Vista®-S Device is a vertebral body replacement device intended for use in the thoracolumbar spine (T1-L5) for partial replacement of a collapsed, damaged or unstable vertebral body due to tumor or trauma (i.e., fracture). The Vista®-S Device is intended for use with supplemental internal spinal fixation systems. The Vista®-S Device may be used with bone graft.

SUBSTANTIAL EQUIVALENCE

Documentation was provided which demonstrated that the Vista®-S Device is substantially equivalent to its predicate devices with respect to intended use/indications for use, materials, technological characteristics and basic principles of operation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 30 2007

Zimmer Trabecular Metal Technology, Inc.
% Ms. Jennifer P. Harakal
Senior Specialist, Regulatory Affairs
10 Pomeroy Road
Parsippany, New Jersey 07054

Re: K070382
Trade Name: Vista®-S Device
Regulation Number: 21 CFR 888.3060
Regulation Names: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Codes: MQP
Dated: February 6, 2007
Received: February 8, 2007

Dear Ms. Harakal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA) application. You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your 510(k) premarket

notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address: http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices
and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Vista®-S Device

Indications for Use:

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Prescription Use __X__ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K070382